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ASCO SPECIAL ARTICLE

Clinical Cancer Advances 2012: Annual Report on Progress Against Cancer From the American Society of Clinical Oncology

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A MESSAGE FROM ASCO'S PRESIDENT

I am delighted to present you with "Clinical Cancer Advances 2012: Annual Report on Progress Against Cancer From the American Society of Clinical Oncology." The American Society of Clinical Oncology (ASCO) uses this opportunity each year to share the steady progress occurring in our understanding and treatment of cancer. For 2012, we offer again an inspiring perspective on clinical cancer advances over the past year, but with a cautionary note: if current threats to federal funding materialize, future progress in cancer research will be seriously undermined.

Continued progress against cancer. As you read the following pages of this report, I hope you will share my unabashed enthusiasm—and pride—in how far we have come. To appreciate what this progress has meant to the millions of people who receive a cancer diagnosis each year, consider the following: (1) two of three people in the United States live at least 5 years after a cancer diagnosis (up from roughly one of two in the 1970s); (2) the nation's cancer death rate has dropped 18% since the early 1990s, reversing decades of increases; and (3) individuals with cancer are increasingly able to live active, fulfilling lives because of better management of symptoms and treatments with fewer adverse effects.

Importance of clinical cancer trials. These dramatic trends—and the advances highlighted in this report—would have been unthinkable without the engine that drives life-saving cancer treatment: clinical cancer research. Advances in technology and in our knowledge of how patient-specific molecular characteristics of the tumor and its environment fuel the growth of cancer have brought new hope to patients. Clinical trials are the key to translating cutting-edge laboratory discoveries into treatments that extend and improve the lives of those with cancer.

But progress is only part of the story. Cancer remains a challenge, with many cancers undetected until their latest stages and others resisting most attempts at treatment. Tragically, cancer still kills more than 500,000 people in the United States every year, and its global burden is growing rapidly.

Bridges to better care. To conquer cancer, we need to build bridges to the future—bridges that will get scientific advances to the patient's bedside quicker, bridges that will enable us to share information and learn what works in real time, and bridges that will improve care for all patients around the world.

At ASCO, we recognize the unique role that oncologists must play. ASCO's "Accelerating Progress Against Cancer: Blueprint for Transforming Clinical and Translational Cancer Research,"[1] published last year, presents our vision and recommendations to make cancer research and patient care vastly more targeted, more efficient, and more effective. We have also launched a groundbreaking initiative, CancerLinQ, that aims to improve cancer care and speed research by drawing insights from the vast pool of data on patients in real-world settings.

Renewing a national commitment to cancer research. We are on the threshold of major advances in cancer prevention, detection, and treatment—but only if, as a nation, we remain committed to this critical endeavor.

The federally funded cancer research system is currently under threat by larger federal budget concerns. Clearly, Congress faces a complex budget environment, but now is not the time to retreat from our nation's commitment to conquering a disease that affects nearly all of us. Bold action must be taken to ensure that we can take full advantage of today's scientific and technologic opportunities.

Please join me in celebrating our nation's progress against cancer and in recommitting ourselves to supporting cancer research. Millions of lives depend on it.

Sandra M. Swain, MD

President

American Society of Clinical Oncology

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EXECUTIVE SUMMARY

Background

Each year, the American Society of Clinical Oncology (ASCO) conducts an independent review of advances in clinical cancer research that have the greatest potential impact on patients' lives. This year's Report, "Clinical Cancer Advances 2012: Annual Report on Progress Against Cancer From the American Society of Clinical Oncology," features 87 studies, 17 of which the Report's editors have designated as major advances.

Although cancer-related deaths have declined tremendously since the early 1990s, cancer remains a leading cause of death worldwide. An estimated 577,000 Americans will lose their lives to cancer in 2012. The large number of advances featured in the Report affirms that clinical cancer research yields remarkable improvements in survival and quality of life for patients with cancer. Many studies highlighted this year capitalized on the growing knowledge about the complexity of cancer to develop sophisticated treatment approaches, such as combining targeted drugs for difficult-to-treat cancers and expanding the use of targeted drugs to multiple forms of cancer that share the same genetic alteration. Major advances over the past year were achieved in the areas of overcoming treatment resistance, personalized medicine, and screening.

It takes years of research effort to achieve advances that extend patients' lives. This progress would not be possible without patient volunteers, dedicated investigators, and substantial public and private research investment. In the United States, the federally funded clinical trials system is essential to progress against cancer. The Clinical Trials Cooperative Group program, sponsored by the National Cancer Institute (NCI), involves approximately 3,100 institutions and places more than 25,000 patients into large clinical trials of promising treatments each year. Many of the significant developments presented in this document were a direct result of clinical research conducted by these cooperative groups. Despite difficult economic times, preserving our nation's investment in cancer research is absolutely necessary to keep the momentum that brings better treatments to the growing number of people with cancer.

This year's Report includes two new sections, Tumor Biology and Quality Cancer Care, which feature studies reflecting the rapid pace of progress in those specialized areas. The Report also highlights the year's most important cancer policy developments and cancer care guidelines that are likely to influence cancer care over the coming years.

Overcoming Treatment Resistance

Some cancers, such as sarcoma, ovarian cancer, and neuroblastoma, are notoriously difficult to treat, and many patients succumb to the disease shortly after diagnosis. A variety of factors contribute to treatment resistance. Some tumors are located in parts of the body that may not be readily accessible to some drugs. Tumors acquire genomic changes, some of which enable them to evade or counter the effects of the treatment. Research results reported this year demonstrate how our understanding of the complex biology of cancer is leading the way to overcoming treatment resistance.

A potentially useful strategy for conquering resistant tumors is to attack more than one target in a molecular pathway that is critical for tumor survival and growth. This can be achieved through use of multitargeted drugs, such as the new agents regorafenib, which has benefited patients with treatment-resistant GI stromal tumors (GISTs) and metastatic colorectal cancer; crizotinib, which has shown promising activity against neuroblastoma and anaplastic large-cell lymphoma (ALCL) in children; and cabozantinib, which seems to slow progression of medullary thyroid carcinoma. An alternative approach is to treat patients with two or more drugs that target the same pathway. There were three reports of improved outcomes for patients with breast cancer using such a strategy (combining two anti–human epidermal growth factor receptor 2 [HER2] agents and combining an aromatase inhibitor with a mammalian target of rapamycin [mTOR] inhibitor) this year. Early trial results showed that combining drugs that target mTOR and insulin-like growth factor receptor (IGF-R) delays progression of metastatic sarcoma resistant to standard treatments.

In addition, novel targeted agents in the class of drugs known as tyrosine kinase inhibitors (TKIs) showed promising activity against treatment-resistant forms of leukemia (ponatinib and ibrutinib), soft tissue sarcoma (pazopanib), and breast cancer (lapatinib).

No Two Tumors Are the Same: The Promise of Precision Medicine

Oncology is rapidly transitioning to an era of precision medicine, where patients receive treatments tailored to the genetic makeup and biology of their tumors. Just as no two patients are the same, it is becoming increasingly clear that no two tumors are exactly the same. In some situations, the genetic variations are not critical to the behavior of a tumor, but in others, these variations may guide specific

Conquer Cancer Foundation

- The Conquer Cancer Foundation of the American Society of Clinical Oncology funded three studies featured is this year's Report: molecular testing that identified new therapeutic targets in squamous cell lung cancer, a prospective trial that identified key factors affecting chemotherapy adverse effects in elderly patients, and a study showing promising activity of a new targeted drug in patients with a chemotherapy-resistant form of sarcoma.
- The mission of the Conquer Cancer Foundation is to conquer cancer worldwide by funding breakthrough research and sharing cutting-edge knowledge. Over nearly 30 years, the Foundation's Grants and Awards Program has provided more than $77 million in funding to support clinical and translational scientists at all levels of their careers, working around the globe. The grants reflect the commitment of the Foundation to address the full spectrum of oncology—focusing on every moment in which cancer touches people's lives—from prevention to end-of-life care, for nearly every cancer type, and funding research in virtually all cancers, including rare ones.

treatment approaches. This year, an important study revealed that there are also dramatic variations in the genomic landscape within a single tumor and among primary and distant tumors (metastases) in the same patient. Researchers now know that even subtle genetic differences can make one tumor responsive and another resistant to the same drug.

Two large-scale genomic profiling studies captured genomic snapshots of more than 1,000 different cancer cell lines, representing much of the tissue-type and genetic diversities of human cancers, and assessed how each of them responded to dozens of different anticancer drugs. This information will enhance rational drug development and speed the discovery of new personalized treatments. New results stemming from The Cancer Genome Project identify potential new drug targets in colorectal cancer, reveal that epigenetic regulation is critical for cancer cell survival, and propose innovative technologies for predicting chemotherapy response in patients with ovarian cancer. Several other studies featured in the Report address the need to identify treatment-resistant patients early, so they can be directed to alternative, potentially effective treatments while being spared the adverse effects of regimens that are not likely to benefit them.

New Insights Into Risks and Benefits of Cancer Screening

It is estimated that approximately one third of all cancer cases could be prevented. The main opportunities for cancer prevention include lifestyle and dietary changes and early detection through screening.

Although routine screening has dramatically reduced the incidence and death rates for some cancers, such as cervical cancer, the value of screening for many other cancers remains uncertain. In fact, in some instances, risks of screening, such as false-positive findings

Table 1. FDA Approvals of Anticancer Agents, October 2011 to October 2012

Generic Name	Trade Name	Manufacturer	Indications	Date of Approval
Newly approved agents				
Axitinib	Inlyta	Pfizer, New York, NY	For treatment of patients with advanced kidney cancer (renal cell carcinoma) who have not responded to other treatments for this type of cancer	January 27, 2012
Vismodegib	Erivedge	Genentech, South San Francisco, CA	For use in patients with locally advanced basal cell cancer who are not candidates for surgery or irradiation and for patients whose cancer has metastasized	January 30, 2012
Pertuzumab	Perjeta	Genentech	For use in combination with trastuzumab and docetaxel as first-line treatment for patients with HER2-positive metastatic breast cancer	June 8, 2012
Carfilzomib	Kyprolis	Onyx Pharmaecuticals, South San Francisco, CA	For treatment of patients with multiple myeloma whose disease has progressed despite at least two prior therapies, including bortezomib and an immunomodulatory agent	July 20, 2012
Ziv-aflibercept	Zaltrap	sanofi-aventis, Bridgewater, NJ; Regeneron Pharmaceuticals, Tarrytown, NY	For use in combination with FOLFIRI for treatment of patients with metastatic colorectal cancer that is resistant to or has progressed after an oxaliplatin-containing regimen	August 3, 2012
Enzalutamide	Xtandi	Medivation, San Francisco, CA	For treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel	August 31, 2012
Regorafenib	Stivarga	Bayer HealthCare Pharmaceuticals, Wayne, NJ	For treatment of patients with metastatic colorectal cancer that has progressed despite standard treatments	September 27, 2012
Expanded indications for existing agents				
Imatinib mesylate	Gleevec	Novartis, Basel, Switzerland	For adjuvant treatment of adult patients after complete gross resection of Kit (CD117) –positive GISTs	January 31, 2012
Pazopanib	Votrient	GlaxoSmithKline, Brentford, United Kingdom	For treatment of patients with advanced soft tissue sarcoma who have received prior chemotherapy	April 26, 2012
Cetuximab	Erbitux	ImClone Systems, Bridgewater, NJ	For use in combination with FOLFIRI chemotherapy for first-line treatment of patients with *KRAS* mutation–negative, EGFR-expressing metastatic colorectal cancer	July 6, 2012
Everolimus	Afinitor	Novartis	For use in combination with exemestane to treat certain postmenopausal women with advanced hormone-receptor positive, HER2-negative breast cancer	July 20, 2012
Vincristine sulfate liposome injection	Marqibo	Talon Therapeutics, South San Francisco, CA	For treatment of adult patients with Ph-negative acute lymphocytic leukemia in ≥ second relapse or whose disease has progressed after ≥ two antileukemia therapies	August 9, 2012

Abbreviations: EGFR, epidermal growth factor receptor; FDA, US Food and Drug Administration; FOLFIRI, fluorouracil, leucovorin, and irinotecan; GIST, GI stromal tumor; HER2, human epidermal growth factor receptor 2; Ph, Philadelphia chromosome.

leading to unnecessary treatments, have been shown to be greater than potential benefits.

For example, this year, a study found that flexible sigmoidoscopy, a technique used to examine the rectum and lower part of the bowel, reduces colorectal cancer incidence and death rates. These findings support wider use of flexible sigmoidoscopy in colorectal cancer screening, but more research is needed to determine how its performance compares with that of colonoscopy. On the other hand, another large study showed that yearly chest x-ray examinations do not reduce lung cancer death rates in the general population.

New Drug Approvals

Between October 2011 and October 2012, on the basis of encouraging results from large clinical trials, the US Food and Drug Administration (FDA) approved seven new anticancer drugs and expanded indications for five existing agents (Table 1) to provide new treatment options for patients with certain forms of myeloma (carfilzomib), leukemia (liposomal vincristine), breast cancer (pertuzumab and everolimus), skin cancer (vismodegib), prostate cancer (enzalutamide), GISTs (imatinib mesylate), colorectal cancer (cetuximab, ziv-aflibercept, and regorafenib), kidney cancer (axitinib), and soft tissue sarcoma (pazopanib).

Almost all of the newly approved drugs are targeted agents, meaning that they are designed to block the activity of specific proteins involved in tumor growth. One agent, vismodegib, marks the first FDA approval of a drug that targets the hedgehog signaling pathway, which plays an important role in tissue growth and repair. The drug is also being tested in clinical trials for colorectal, stomach, and pancreatic cancers.

About Clinical Cancer Advances

ASCO developed this Annual Report, now in its eighth year, to document the important progress being made in clinical cancer research and to highlight emerging trends in the field. The Report serves to outline to the public progress achieved against cancer by reviewing the major advances in clinical cancer research and care each year.

This report was developed under the direction of a 21-person editorial board composed of prominent oncologists with expertise in areas pertinent to each section of the Report. The editors reviewed research published in peer-reviewed scientific or medical journals and presented at major scientific meetings over a 1-year period (October 2011 to September 2012).

The advances included in this Report are categorized as major and notable. Major advances are considered practice changing and had to have been published in a peer-reviewed journal and/or report on a treatment that received FDA approval in the past year. Notable advances are promising clinical research results that are not immediately applicable to practice, either because a drug is not yet FDA approved or because the information is only available in abstract form (ie, has not yet appeared in a peer-reviewed publication).

The research reviewed in this Report covers the full range of clinical research disciplines: epidemiology, prevention, screening, early detection, treatment (including surgery, chemotherapy, radiation, targeted therapy, immunotherapy, and personalized therapy), patient and survivor care (including end-of-life care and elderly patient care), biomarkers, tumor biology, and cancer disparities.

This Report is intended for anyone with an interest in cancer care, including the general public, news media, patients, caregivers, oncologists and other medical professionals, policymakers, and cancer advocacy organizations.

About ASCO

ASCO is the world's leading professional organization representing physicians who care for people with cancer. With more than 30,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs, and peer-reviewed journals. For ASCO information and resources, visit http://www.asco.org. Cancer information for the lay public is available at http://www.cancer.net.

BLOOD AND LYMPHATIC CANCERS

Cancers of the blood and lymphatic system include leukemia, lymphoma, and multiple myeloma. The most common blood cancer, leukemia, includes several distinct diseases: acute lymphocytic leukemia (ALL), chronic lymphocytic leukemia (CLL), acute myelogenous leukemia (AML), and chronic myelogenous leukemia (CML).

This year, investigators reported encouraging results in clinical trials that tested new chemotherapies, targeted drugs, antibodies, and antibody-drug combinations. One trial resurrected interest in a previously withdrawn AML drug, proposing a new dosing scheme that seems safer for patients yet still effective. Long-term results of a large trial confirmed that an antibody-chemotherapy drug combination is more effective and better tolerated than the standard antibody-chemotherapy combination in mantle-cell and indolent lymphomas. And finally, results of three early-phase trials point to promising new therapies for treatment-resistant CML, ALL, and CLL.

Major Advances

Lenalidomide maintenance therapy delays multiple myeloma relapse after stem-cell transplantation. Since the introduction of high-dose chemotherapy, outcomes have improved considerably for patients with multiple myeloma. However, in most of those patients,

ASCO's CancerProgress.Net: An Interactive History of Cancer Research Advances

- CancerProgress.Net was launched in 2011 to mark the 40th anniversary of the US National Cancer Act, which led to major new investments in cancer research and significant increases in cancer survival. The site is intended to provide a dynamic and interactive history of progress against cancer, expert perspectives on remaining challenges, and other useful tools.
- The central feature of the site—the interactive timeline—was developed under the guidance of an editorial board of 17 of the nation's leading oncologists and will be updated over time with additional cancer types, significant new advances, and helpful videos, links, and images.

cancer returns within 10 years of receiving high-dose chemotherapy and stem-cell transplantation, because chemotherapy typically fails to eradicate all myeloma cells. Several treatments for controlling growth of residual myeloma cells after transplantation (maintenance of remission) have been explored, but their use has thus far been hindered by inconsistent effectiveness and harmful adverse effects.

However, results of two placebo-controlled phase III trials reported this year indicate that lenalidomide may be able to delay relapses in patients with multiple myeloma after stem-cell transplantation. In the first study, 615 patients age younger than 65 years were randomly assigned to maintenance treatment with either lenalidomide or placebo until relapse.[2] On average, the disease returned after 41 months with lenalidomide therapy versus 23 months with placebo. After 4 years of follow-up, more than 70% of patients were alive in both groups. In the second study, 460 patients with multiple myeloma age younger than 71 years were randomly assigned to receive lenalidomide or placebo.[3] The median time to disease progression was 46 months in the lenalidomide group and 27 months in the placebo group. Lenalidomide also increased overall survival; a total of 35 deaths occurred in the lenalidomide group compared with 53 deaths in the placebo group. In both studies, the benefit of lenalidomide was seen among all patient subgroups and was independent of patient age, prior use of lenalidomide, and disease stage. However, lenalidomide was also associated with more adverse effects and higher incidence of second cancers compared with placebo (7% to 8% *v* 3% to 4%). These results provide compelling evidence of improved progression-free survival with lendalidomide maintenance therapy. But given the uncertainty of the overall survival benefit and considerable risks associated with the treatment, including myelodysplastic syndrome and AML, the risks and benefits should be carefully assessed to maximize both survival and patients' quality of life. The association of lenalidomide with second malignancies in patients with myeloma continues to be evaluated.

Notable Advances

Gemtuzumab ozogamicin added to standard chemotherapy improves survival of older patients with AML. Gemtuzumab ozogamicin was widely used to treat AML from 2000 until 2010, when it was withdrawn from the market based on concerns that it does not provide enough benefit compared with standard therapy to justify its associated serious risks, including death. Gemtuzumab ozogamicin consists of an antitumor antibiotic calicheamicin that is chemically linked to an antibody that targets CD33, a protein found on the surface of most immature AML WBCs (blasts) and myeloid precursor cells.

This year, investigators reported data from a phase III trial that sought to determine if the addition of gemtuzumab ozogamicin to standard induction (initial) and consolidation chemotherapy could improve outcomes of older patients with AML.[4] Consolidation therapy is used to kill any cancer cells left in the body after initial therapy.

In the study, 280 patients between ages 50 and 70 years with newly diagnosed with AML were randomly assigned to treatment with chemotherapy alone or chemotherapy plus gemtuzumab ozogamicin. Gemtuzumab ozogamicin was administered on a novel dosing schedule during induction; fewer doses were administered during consolidation. At 2 years, the proportion of patients who remained free of disease was twice as high in the gemtuzumab ozogamicin group of patients, an estimated 40.8% versus 17.1%. Overall and recurrence-free survival rates were also significantly improved in the gemtuzumab ozogamicin group (53.2% *v* 41.9% and 50.3% *v* 22.7%). However, this benefit was not observed in patients with high-risk subtypes of the disease.

Although the addition of gemtuzumab ozogamicin increased the hematologic toxicity associated with chemotherapy, unlike previous studies, this trial found there was no increase in induction mortality or death in remission. This study, along with three other European trials reported at the 53rd Annual Meeting of the American Society of Hematology in December 2011, shows the addition of gemtuzumab ozogamicin to chemotherapy seems to improve outcomes and even prolong the survival of older patients with AML. Gemtuzumab ozogamicin is currently only available as an investigational agent. Pfizer is considering its next steps with this important antibody-drug conjugate for older adults with AML.

New chemotherapy-antibody combination delays disease progression in lymphoma. Mantle-cell lymphoma is a rare but difficult-to-treat form of lymphoma. Even with treatment, patients live a median time of just 3 to 6 years after diagnosis. A chemotherapy drug called bendamustine has previously been used in combination with the antibody rituximab to treat relapsed and recurrent mantle-cell lymphoma and indolent (slow growing) lymphoma, but the efficacy of this combination in previously untreated patients has been unclear.

Long-term results of a phase III trial that explored the efficacy of bendamustine plus rituximab (B-R) versus CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) chemotherapy plus rituximab (CHOP-R) in 514 patients with indolent and mantle-cell lymphomas were reported this year.[5] The median patient age was 64 years. Investigators found that B-R extended the median time to disease progression by more than 3 years (69.5 months with B-R *v* 31.2 months with CHOP-R) and was better tolerated than CHOP-R. Overall survival did not differ between the two treatment groups, partly because nearly half of the CHOP-R patients whose disease continued to progress were permitted to receive B-R, and partly because survival for indolent lymphomas tends to be long (10 to 15 years).

This study demonstrates that B-R is superior to the standard treatment (ie, CHOP-R) for patients with previously untreated indolent lymphoma and elderly patients with mantle-cell lymphoma. Once the final report of this trial is published, the results are expected to change clinical practice, especially in the United States, where the CHOP-R regimen has been widely used.

Ponatinib is active in treatment-resistant CML and ALL. Introduction of BCR/ABL TKI drugs revolutionized the treatment of patients with CML and Philadelphia chromosome (Ph) –positive ALL. However, patients harboring a specific alteration in the BCR/ABL protein T315I are resistant to the TKI drugs. But results from an ongoing phase II study showed that a new, rationally designed TKI drug, ponatinib, is active in this group of patients.[6]

In the study, nearly all of the 449 patients enrolled had experienced failure of two or more previous treatments with BCR/ABL TKIs. Remissions occurred in 65% of patients with chronic-phase CML with the T315I alteration, and hematologic responses (recovery of healthy blood cell counts) were observed in 37% of patients with Ph-positive ALL with T315I. These results suggest that ponatinib is an active agent for these two populations of patients.

Small trial reveals a potential new initial treatment for elderly patients with CLL. The standard therapy for CLL, fludarabine, is effective in elderly patients, but it carries significant risk of adverse effects, including treatment-related death. Therefore, older patients

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